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ANNUAL SURVEY REPORT ETHICAL PHARMACEUTICAL INDUSTRY OPERATIONS 1978-1979

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Annual Survey Report
PMA 1978-1979

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Foreword

The Pharmaceutical Manufacturers Association (PMA) is a nonprofit trade association representing 143 member firms. These firms produce most of the ethical pharmaceuticals in the United States and a substantial portion of the world supply. Many also manufacture medical devices and diagnostic products.

This 19th Annual Survey Report is designed to provide a variety of information on these industries to business executives, financial analysts, educators and other interested groups. PMA expresses its appreciation to member firms for supplying the information on which the report is based.

Survey questions are periodically updated and the scope of the survey expanded or reduced to reflect changing priorities, but an effort is made to maintain continuity. Comparison among surveys can be made in most categories. An addition to the statistics presented this year is the division of ethical pharmaceutical sales into "prescription drugs" and "over-the-counter items". A report on sales and research activity in the medical device and diagnostic products area will be published separately.

Responses to surveys are reasonably uniform and consistent. There are minor variations, however, from year to year. To compensate for these, adjustments are made based on supplementary data available to PMA from other sources.

Some survey responses are "collective" responses, due to the nature of the membership of the Association. This means that a parent firm provides data on relevant operations for all its corporate divisions and subsidiaries. Most of these "multiple members"

are identifiable in their own right and generally appear on the PMA membership list. In presenting data in the report, responses are expressed in terms of "companies" or corporate entities. Each response or "company" may represent one or more PMA members or related firms.

Although this is a membership survey, nonmember firms are represented in selected operational totals by estimate, based on data obtained from other sources. For example, aggregated human-use dosage form drug sales have been extrapolated to represent the entire industry. But extrapolation has not been applied to bulk sales, veterinary use pharmaceuticals, foreign data or R & D.

No adjustment has been made for inflation; data are presented in current dollars for manufacturers' sales and R & D expenditures. It should be noted that prescription pharmaceutical prices, at manufacturers' levels as well as retail, in contrast to most other product prices in the U.S. economy, have remained relatively stable for many years. The producer price index (1967 = 100) for ethical pharmaceuticals in 1978 was 131.9 (in contrast to 209.3 for "all commodities"). Thus sales-dollar trends provide a closer representation of expansion in physical product volume for pharmaceuticals than for most other industries where there has been substantial inflation.

The format for presenting the data has been simplified this year: highlights and comparisons with previous years directly precede each table. This should facilitate the use of the material offered in the report.

TRENDS

1978-1979 Pharmaceutical Industry Operations

- Global Sales, Ethical Pharmaceuticals, Human and Veterinary Use:
  1978 $17 billion, up 16% from 1977
  1979 $19 billion, (estimated), up 13% from 1978
- U.S. Sales, Human Use, Dosage Form Pharmaceuticals:
  1978 $9 billion, up 11% from 1977
  1979 $10 billion (estimated), up 11% from 1978
- Global R&D Ependitures for Human and Veterinary Use Pharmaceuticals:
  1978 $1.4 billion, up 10% from 1977
  1979 $1.6 billion (budgeted), up 14% from 1978

Table 1

U.S. Headquartered Firms' Sales and R & D Expenditures, 1954-1979 (millions of dollars)

1

Year	U.S. Sales[a]	Global Sales Human and Veterinary[b]		Global R & D[c]
	Human Dosage	*Dosage Only*	*Dosage & Bulk*	*Human & Veterinary*
1979[d]	10,154	na	19,202	1,600
1978	9,156	16,040	17,008	1,404
1977	8,233	13,896	14,674	1,276
1976	7,669	12,832	13,572	1,164
1975	6,895	11,543	12,183	1,062
1974	6,083	10,120	10,726	942
1973	5,507	8,755	9,191	825
1972	5,018	7,827	8,181	726
1971	4,667	7,020	7,838	684
1970	4,322	6,442	6,853	619
1969	4,008	5,832	6,208	550
1968	3,655	5,280	5,665	495
1967	3,226	4,707	5,102	461
1966	3,011	4,256	4,660	416
1965	2,779	3,841	4,219	365
1964	2,479	3,405	3,717	310
1963	2,317	3,152	3,469	292
1962	2,199	2,932	3,236	259
1961	1,954	2,685	2,992	245
1960	1,905	3,600	na	212
1959	1,850	2,500	na	197
1958	1,802	2,400	na	170
1957	1,742	2,200	na	127
1956	1,676	1,900	na	105
1955	1,457	1,650	na	91
1954	1,252	1,500	na	78

[a] U.S. sales of finished prescription and "otc ethical dosage forms."

[b] Global sales are defined to include total ethical pharmaceutical sales within the United States, exports to nonaffiliated firms and sales abroad of U.S. affiliates.

[c] Global R & D includes all ethical pharmaceutical research and development financed or conducted by U.S. pharmaceutical companies in the U.S. and abroad, and in the U.S. only by U.S. based subsidiaries of foreign owned firms.

[d] PMA estimates based on member company budgeted figures or estimates.

Source: PMA Annual Surveys.

SALES

1978 Sales in the United States and Abroad

- U.S. sales volume rose 12%; foreign sales volume rose 22%.
- U.S. sales accounted for 58% of volume for U.S. based manufacturers; foreign sales accounted for 42%, up from 28% a decade ago.
- Human use dosage forms constitute 91% of all sales, U.S. and Foreign.
- Exports amounted to $1,065 million, up 12%.

Tables 2 and 3

Ethical Pharmaceuticals Sales Growth, 1977-1978 (millions of dollars) **2**

Year	Domestic Sales	Percent Change	Foreign Sales	Percent Change	Total	Percent Change
1977	$8,863.9		$5,810.5		$14,674.4	
1978	$9,916.9	+11.9%	$7,091.0	+22.0%	$17,007.9	+15.9%

1978 Sales by Dosage Form

- Prescription Drugs accounted for 80% of U.S. sales in the human use, dosage form category; over-the-counter ethical products accounted for 15%; and the remainder came from sales of biologicals, diagnostics and other products.
- Government Sales of ethical pharmaceuticals constituted 8% of the total; and 83% of this sum was for prescription drugs.

Table 4

Domestic Sales of Dosage Form, Human Use Ethical Pharmaceuticals, 1978 (millions of dollars) **4**

Dosage Form Human Use	To Private Sector	To Government	Total Domestic Sales
Prescription Legend[a]	$6,684.5	$611.5	$7,296.0 (79.7%)
Over-the-Counter Ethical[b]	1,347.0	51.6	1,398.6 (15.3%)
Biologicals[c]	210.5	44.2	254.7 (2.8%)
Diagnostic Products[d]	75.8	14.7	90.5 (1.0%)
Other	101.0	14.7	115.7 (1.2%)
Total, Dosage Form, Human Use	$8,418.8	$736.7	$9,155.5 (100.0%)

[a] *Prescription Legend* – A drug product which by Federal law is available only by prescription by a licensed physician.
[b] *Over-the-Counter Ethical* – A drug product sold over the counter but primarily promoted to the professions.
[c] *Biologicals* – Bacterial and virus vaccine, antigens, antitoxins, toxoids, and analogous products (such as allergenic extracts), serums, plasmas, and other blood derivatives for human use.
[d] Dosage form, *diagnostic agents* for *in-vivo* use.

1978 Sales by Geographic Area

- Europe accounted for 47% of foreign sales, Latin America 20%, the Far East 18%, and the rest of the world the remaining 15%.

Table 5

Distribution of Foreign Sales* by Geographic Area, 1978 **5**

Area	Percentage of Total Foreign Sales
Canada	6.6%
Latin American (Central America, South America, excluding Cuba)	19.9
Western Europe (excluding Turkey, Yugoslavia and Albania; including Greece and Scandinavia)	47.3
Middle East and Africa	6.8
Far East and Pacific (from Pakistan to Pacific Islands, from Japan to New Zealand)	18.4
Socialist Bloc (including Eastern Europe, U.S.S.R., Yugoslavia, Albania, People's Republic of China, Laos, Cambodia and Vietnam)	1.0
TOTAL	100.0%

*Sales made abroad, only. Exports are excluded.

Ethical Pharmaceutical Sales[a], Domestic and Foreign: Shares of End-Use Totals, 1978 (millions of dollars)

3

	Domestic U.S. Sales			Foreign Sales			Total	Sales for Export
	To Private Sector	To Governments	Total Domestic Sales	Exports to Other Firms	Sales Abroad[b]	Total Foreign Sales		Intra-Firm Transactions[c]
Dosage Form Human Use	$8,418.8 (54.6%)	$736.7 (4.8%)	$9,155.5 (59.4%)	$220.0 (1.4%)	$6,050.0 (39.2%)	$6,270.0 (40.6%)	$15,425.5 (100.0%)	$ 252.3
Dosage Form Veterinary Use	272.1 (44.3%)	.9 (.1%)	273.0 (44.4%)	14.2 (2.3%)	327.1 (53.3%)	341.3 (55.6%)	614.3 (100.0%)	53.0
Bulk Human Use	253.0 (45.9%)	1.6 (.3%)	254.6 (46.2%)	87.4 (15.9%)	209.1 (37.9%)	296.5 (53.8%)	551.1 (100.0%)	385.9
Bulk Veterinary Use	233.8 (56.0%)		233.8 (56.0%)	7.4 (1.8%)	175.8 (42.2%)	183.2 (44.0%)	417.0 (100.0%)	44.5
TOTAL	$9,177.7 (54.0%)	$739.2 (4.3%)	$9,916.9 (58.3%)	$329.0 (1.9%)	$6,762.0 (39.8%)	$7,091.0 (41.7%)	$17,007.9 (100.0%)	$ 735.7

[a]Sales are before deducting cash discounts and other marketing expenses, but after returns and allowances (domestic returns and allowances totaled $253 million in 1978).

Export sales are f.o.b. U.S. port. A majority of the firms reported most domestic U.S. sales were made f.o.b. purchaser's location or equivalent. The above domestic U.S. dosage form sales to the private sector are gross at invoice price. For "f.o.b. manufacturer's plant" totals, deduct $292 million ($146 million transportation-out and $146 million company branch or field warehousing).

[b]Sales abroad refers to sales in a foreign area by subsidiaries or other corporate operations and excludes U.S. export sales to other firms. Excluded also are sales outside the U.S. by foreign-owned firms that have subsidiaries in the U.S. as PMA member firms.

[c]Sales for Export Intra-Firm Transactions are sales to own International Division or for export to subsidiary abroad and are included as part of cost in Sales Abroad. Addition of the two export columns will provide aggregate ethical pharmaceutical exports.

1978 Sales by Class of Customer

- Sales to wholesalers were up, but sales were down to retailers, federal hospitals, manufacturers, repackagers, and others.
- Wholesalers now account for more than half of all direct sales.
- Total hospital sales remained about the same, 22.6% in 1978 as against 22.3% in 1977.

Tables 6 and 7

Ethical Pharmaceuticals Manufacturers' Direct Human Use Dosage Form Sales, in the United States, 1977-1978 (millions of dollars)

6

Class of Customer	Sales 1977	Market Share 1977	Sales 1978	Market Share 1978
Wholesalers	$4,042.5	49.1%	$4,705.9	51.4%
Retailers	2,099.5	25.5	2,087.5	22.8
Private Hospitals	1,243.2	15.1	1,464.9	16.0
State and Local Government Hospitals	370.5	4.5	384.5	4.2
Federal Hospitals	222.3	2.7	219.7	2.4
Other Federal Government	107.0	1.3	128.2	1.4
Practitioners	90.6	1.1	109.9	1.2
Manufacturers, Repackagers and Other Direct Sales	57.6	.7	54.9	.6
TOTAL	$8,233.2	100.0%	$9,155.5	100.0%

Ethical Pharmaceuticals Manufacturers' Direct Human Use Dosage Form Sales in the United States by Class of Customer, 1968-1978 (even years, percentage share of sales)

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Class of Customer	1968	1970	1972	1974	1976	1978
Wholesalers	47.5%	46.9%	45.6%	45.2%	48.5%	51.4%
Retailers	29.2	29.0	29.4	28.1	26.4	22.8
Private Hospitals	11.9	13.6	14.6	15.6	14.8	16.0
State and Local Government Hospitals	4.2	3.9	4.7	4.8	4.5	4.2
Federal Hospitals	3.4	3.0	2.6	2.6	2.5	2.4
Other Federal Government	1.2	1.0	1.1	1.2	1.3	1.4
Practitioners	1.9	1.6	1.6	1.5	1.2	1.2
Manufacturers, Repackagers, and Other Direct Sales	.7	1.0	.4	1.0	.8	.6
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

1978 Sales by Product Class

- Products acting on the central nervous system continued to represent the largest product sales category, accounting for 24.8% of domestic dosage form sales.
- Other product classes, in order of sales rank, were antiinfectives (15.7%), gastrointestinal and genitourinary systems (12.5%), neoplasms and endocrine system (10.2%), vitamins and nutrients (10.2%) and cardiovasculars (9.9%).
- Over-the-counter ethicals constitute over one-third of the classes for vitamins, respiratory system, and dermatological drugs.
- In foreign sales anti-infectives are first, followed by drugs for the central nervous system, and respiratory system. These three groups account for over half of the sales abroad.

Tables 8 and 9

Foreign Sales by Product Class, Dosage Form Ethical Drugs for Human Use, 1977-1978[a] **9**

Product Class	Relative Share of Sales 1977	Relative Share of Sales 1978	%Change Dollar Sales 1977-1978[b]
Anti-Infectives	25.9%	25.1%	16.7%
Central Nervous System	14.4	14.5	21.5
Respiratory System	12.8	12.2	14.4
Gastrointestinal and Genitourinary	8.4	10.8	56.1
Neoplasms and Endocrine	10.8	10.2	13.7
Cardiovasculars	8.6	9.2	28.4
Vitamins and Nutrients	6.0	5.5	10.2
Dermatologicals	2.5	2.8	32.7
Biologicals	1.2	1.2	14.2
Diagnostic Agents	.6	.1	–82.3
Other Pharmaceutical Preparations	8.8	8.4	–
	100.0%	100.0%	

[a]Same companies for 1977-1978, representing approximately 87 percent of foreign sales in 1978.
[b]Based on actual dollar sales.

Industry Employment

- Pharmaceutical industry employment reached 307,500 persons worldwide.
- Percentage employed abroad decreased from 43% in 1977 to 42% in 1978. In 1975 and 1976, 44% were employed abroad.
- Half of all U.S. employees were in production, 22% in marketing and distribution, and the rest in medical, R&D, and administration. Five years ago, 47% were in production, 24% in marketing and distribution.
- Ten percent of the U.S. work force was engaged in production and distribution activities related to export and other international business.

Tables 10 and 11

Domestic & Foreign Employment, Ethical Pharmaceuticals, 1978

10

U.S. Employment	178,800
Production Workers	92,900
Marketing & Distribution	39,000
Medical Research & Development	23,400
Administrative & Others	23,500
Foreign Employment	128,700
TOTAL	307,500

Employment, 1977 and 1978

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	1977	1978
United States	168,900	178,800
Foreign	127,500	128,700
TOTAL	296,400	307,500

Sales in 1979

- PMA estimates that worldwide sales by U.S. based firms increased by $2 billion in 1979, to $19 billion.
- U.S. sales represented an estimated $11 billion, and foreign sales an estimated $8 billion.
- 1978 sales projections (made in mid-1978) exceeded actual results by 1.4% in the U.S., but fell short by 7% of actual foreign sales.

Tables 12 and 13

Ethical Pharmaceutical Sales, 1978 Actual and 1979 Estimated (millions of dollars) **12**

Sector	1978 Actual	1979 Estimated*	Percentage Growth Estimate
Domestic Sales	$ 9,916.9	$10,997.8	10.9
Foreign Sales	7,091.0	8,204.3	15.7
TOTAL SALES	$17,007.9	$19,202.1	12.9

*Estimates were made mid-1979.

Estimates and Actual Sales, 1978 (millions of dollars) **13**

	1978 Sales as Estimates*	Actual 1978 Sales	Difference %
Domestic Sales	$10,060.5	$ 9,916.9	−1.4
Foreign Sales	6,618.2	7,091.0	+7.1
TOTAL SALES	$16,678.7	$17,007.9	+1.9

*Estimates were made mid-1978

R&D

1978 Research and Development

- Total R&D expenditures reached $1.4 billion, up 10% from 1977.
- 94% of company R&D funds were spent on human-use pharmaceuticals, and 6% on animal-use, representing a slight increase in the relative share for human-use research.
- There was an 11% increase in human use research, and a 2% increase in veterinary use research expenditures.
- Extramural expenditures for human-use drug research in the U.S. went up 32%. Foreign R&D expenditures showed an opposite trend—an increase in intramural over extramural research.
- Government contracts were down from $10 million to $7 million. They represented only 1% of R&D expenditures.

Table 14

R & D Expenditures for Ethical Pharmaceuticals: 1977, 1978 Actual and 1979 Budgeted PMA Member Firms (millions of dollars)

14

	1977 Actual	1978 Actual	1979 Budgeted
Company-Financed R & D Expenditures for Human-Use Pharmaceuticals:			
Amount spent in United States	$ 984.1	$1,089.2	$1,225.2
Within firm	862.7	929.3	1,028.7
Outside firm	121.4	159.9	196.5
Amount spent in foreign countries	197.7	222.0	269.9
Within firm	166.3	198.0	239.1
Outside firm	31.4	24.0	30.8
TOTAL Human-Use R & D	$1,181.8	$1,311.2	$1,495.1
Company-Financed R & D Expenditures for Veterinary-Use Pharmaceuticals:			
Amount spent in United States	$ 68.9	$ 69.9	$ 78.1
Within firm	61.4	62.3	70.2
Outside firm	7.5	7.6	7.9
Amount spent in foreign countries	15.4	15.9	19.6
Within firm	14.5	15.2	18.6
Outside firm	.9	.7	1.0
TOTAL Veterinary R & D	$ 84.3	$ 85.8	$ 97.7
TOTAL Company-Financed R & D Pharmaceuticals	$1,266.1	$1,397.0	$1,592.8
U.S. Government Grants and Contracts for Company-Conducted Pharmaceutical R & D	$ 10.0	$ 7.0	$ 6.8
TOTAL Expenditures for Pharmaceutical R & D	$1,276.1	$1,404.0	$1,599.6

1978 Research and Development Expenditures Abroad

- There was a continued increase in R&D spending abroad, representing 17% of total expenditures. This compares with 16.8% in 1977.
- The rate at which R&D spending abroad has been increasing may be leveling off. The percent change for human use drug research 1977 to 1978 was 12.3%. The change from 1976 to 1977 was 19.9%.

Tables 15 and 16

Domestic Sales by Product Class, Dosage Form Ethical Drugs for Human Use, 1978 (millions of dollars)

Product Class	Prescription Drugs Sales	Prescription Drugs Market Share	Over-The-Counter Ethicals Sales	Over-The-Counter Ethicals Market Share	Total Sales	Total Market Share
Central Nervous System	$2,052.1	28.1%	$ 105.1	7.5%	$2,157.2	24.8%
Anti-Infectives	1,338.7	18.3	30.2	2.2	1,368.9	15.7
Gastrointestinal and Genitourinary	776.0	10.6	307.8	22.0	1,083.8	12.5
Neoplasms and Endocrine	880.6	12.1	9.1	.6	889.7	10.2
Vitamins and Nutrients	330.4	4.6	553.0	39.5	883.4	10.2
Cardiovasculars	861.1	11.8	(<.1)	(<.1)	861.1	9.9
Respiratory System	465.4	6.4	245.7	17.6	711.1	8.2
Dermatologicals	152.7	2.1	110.1	7.9	262.8	3.0
Other	439.0	6.0	37.6	2.7	476.6	5.5
TOTAL	$7,296.0	100.0%	$1,398.6	100.0%	$8,694.6	100.0%

R & D Expenditures, Pharmaceuticals, 1976, 1977, 1978 (millions of dollars)

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	1976		1977		1978	
	Amount	Change 1975-1976	Amount	Change 1976-1977	Amount	Change 1977-1978
Company-Financed, for Human-Use Pharmaceuticals:						
Amount spent in United States	$902.9	+ 9.0%	$984.1	+ 9.0%	$1,089.2	+10.7%
Amount spent in foreign countries	$164.9	+13.8%	$197.7	+19.9%	$ 222.0	+12.3%
Company-Financed, for Veterinary-Use Pharmaceuticals:						
Amount spent in United States	$ 71.4	+ 8.3%	$ 68.9	- 3.5%	$ 69.9	+ 1.5%
Amount spent in foreign countries	$ 15.4	+17.6%	$ 15.4	no change	$ 15.9	+ 3.2%

Domestic and Foreign Shares of Company-Funded R & D Expenditures, 1968, 1970, 1972-1978 (percentages)

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R & D Expenditures, Human- and Animal-Use Pharmaceuticals	1968	1970	1972	1973	1974	1975	1976	1977	1978
Domestic	91.3%	91.4%	90.1%	85.6%	84.2%	85.0%	84.4%	83.2%	83.0%
Foreign	8.7	8.6	9.9	14.4	15.8	15.0	15.6	16.8	17.0
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

1978 Research and Development Distribution of Expenditures

- The share of expenditures devoted to human use drug research continued to increase with offsetting decreases in veterinary drug research. Human use drug research accounted for 91.83% of total expenditures in 1972, 93.39% in 1978, and 93.47% in 1979 budgets.
- The share of expenditures for intramural research in the United States for human use drugs is decreasing, with offsetting increases in extramural research.
- Companies with large R&D budgets spend more abroad than companies with small R&D expenditures; those with an R&D outlay under $10 million spent 4.4% or less of their funds abroad. Companies with the largest R&D expenditures spent 17% abroad. The same holds true for companies classified by size of global sales.
- Large companies tend to allocate funds for veterinary research; smaller companies show little or no research for veterinary medicines. Thus companies with global sales over $100 million, spent 5.5% of their R&D funds for veterinary drug research; this percentage decreased to 2.6% for companies with global sales between $30 and $100 million, and companies with sales under $30 million, showed no veterinary drug research.

Tables 17, 18 and 19

Research by Geographic Area, 1978

- Over two thirds or 69% of the research funds spent abroad were spent in Western Europe.
- The Far East accounted for 19% of foreign expenditures, Latin America for 6.3%, and Canada for 5.1%.

Table 20

1978 Research and Development Expenditures by Company Size Groups

- The share of total R&D expenditures represented by companies spending over $10 million for R&D decreased from 94.3% in 1977 to 93.1% in 1978.

Table 21

Distribution of R & D Expenditures Abroad by Geographic Area, 1978

20

Area	Percentage of Total
Canada	5.1%
Latin American (Central America, South America, Caribbean, excluding Cuba)	6.3
Western Europe (excluding Turkey, Yugoslavia and Albania; including Greece and Scandinavia)	68.6
Middle East and Africa	1.4
Far East and Pacific (from Pakistan to Pacific Islands, from Japan to New Zealand)	18.5
Socialist Bloc (including Eastern Europe, U.S.S.R., Yugoslavia, Albania, People's Republic of China, Laos, Cambodia and Vietnam)	.1
TOTAL	100.0%

Size Distribution of Company-Funded Global R & D Expenditures for Ethical Pharmaceuticals, 1977-78

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R & D Expenditures by Size Groups	Percentage of Dollar Expenditures 1977	1978
Over $30 million	77.9%	77.8%
$10-30 million	16.4	15.3
$1-$9.9 million	5.6	6.4
Under $1 million	.1	.5
TOTAL	100.0%	100.0%

1978 Research and Development by Allocation of Expenditures to New Product Research

- 81% of R&D funds are spent for research and development of new products; 19% goes for improvement of existing products.
- The recent trend to greater shares of R&D allocated to new product research peaked in 1977, at 83%, declining to 81% in 1978. The share had steadily increased from 76% in 1972.
- Abroad, the ratio of new product/existing product expenditures was 76/24, up substantially from 68/32 in 1977.

Tables 22 and 23

Company-Financed R & D Expenditures in the United States, 1978 (percentages) — 22

	Human- and Veterinary-Use R & D
Research for the Advancement of Scientific Knowledge and Development of New Products and Related Services	81.1%
Research Oriented to Significant Improvement and/or Modification of Existing Products	18.9
TOTAL	100.0%

Company-Financed R & D Expenditures in Foreign Countries, 1978 (percentages) — 23

	Human- and Veterinary-Use R & D
Research for the Advancement of Scientific Knowledge and Development of New Products and Related Services	75.7%
Research Oriented to Significant Improvement and/or Modification of Existing Products	24.3
TOTAL R & D Abroad	100.0%

1978 Research and Development Allocation of Expenditures by Product Class

- Two-thirds of the funds went for investigations related to infections, central nervous system, neoplasms and the heart.
- Anti-infective product research led with 19% of the total.
- Increases in 1978 went to cardiovasculars (9%), and neoplasms and endocrine system (4%).
- Abroad, anti-infectives also occupy first place in research allocation, followed by cardiovasculars, the central nervous system, gastrointestinal, and neoplasms and endocrine system.

Tables 24 and 25

U.S. R & D Expenditures, Pharmaceuticals, by Product Class, 1977-1978*

24

Ranking 1977	Ranking 1978	Product Class	Percentage Share of R & D Dollar 1977	Percentage Share of R & D Dollar 1978
1	1	Anti-infectives	19.2%	18.9%
2	2	Central Nervous System and Sense Organs	17.0	16.8
4	3	Cardiovasculars	15.2	16.6
3	4	Neoplasms, Endocrine System and Metabolic Diseases	15.7	16.4
5	5	Gastrointestinal and Genitourinary System	6.0	6.2
6	6	Respiratory	4.0	4.0
8	7	Biologicals	3.1	3.2
7	8	Dermatologicals	3.2	3.1
9	9	Vitamins	2.5	2.4
10	10	Diagnostic (in vivo)	.8	.5
		Other	6.3	5.6
		Veterinary Preparations	6.6	5.9
		Veterinary Biologicals	.4	.4
			100.0%	100.0%

*Same companies, 1977 and 1978

R & D Expenditures Abroad, Pharmaceuticals, by Product Class, 1977-1978*

25

Ranking			Percentage Share of R & D Dollar	
1977	1978	Product Class	1977	1978
1	1	Anti-infectives	25.0%	24.1%
2	2	Cardiovasculars	18.4	21.4
3	3	Central Nervous System and Sense Organs	12.8	13.2
5	4	Gastrointestinal and Genitourinary System	7.9	10.5
4	5	Neoplasms, Endocrine System and Metabolic Diseases	9.4	9.0
6	6	Respiratory	2.8	2.9
7	7	Dermatologicals	1.8	2.4
8	8	Biologicals	1.1	1.5
9	9	Vitamins	.7	.8
10	10	Diagnostics (in vivo)	.1	<.1
		Other	11.6	6.4
		Veterinary Preparations	8.0	7.8
		Veterinary Biologicals	.4	—
			100.0%	100.0%

*Same companies, 1977 and 1978

1978 Research and Development Allocation of Expenditures by Function

- Over half of all R&D expenditures is allocated to Biological Screening and Pharmacological Testing, Clinical Evaluation, and Synthesis and Extraction.
- The largest share, 19% is spent on Biological Screening and Pharmacological Testing.

Table 26

Distribution of U.S. R & D Expenditures for Ethical Pharmaceuticals by Function, 1978

26

Function	Percentage of Total
Biological Screening and Pharmacological Testing	18.8%
Clinical Evaluation: Phases I, II, III	16.5
Synthesis and Extraction	16.3
Pharmaceutical Dosage Formulation and Stability Testing	10.1
Toxicology and Safety Testing	10.0
Process Development for Manufacturing and Quality Control	9.2
Clinical Evaluation: Phase IV	4.8
Regulatory, IND and NDA Preparation, Submission and Processing	3.6
Bioavailability Studies	2.2
Other	8.5
TOTAL	100.0%

R & D Expenditures for Ethical Pharmaceuticals, Allocation of Funds (percentages) 1972, 1977, 1978 and 1979 (Budgeted)

Category of R & D Expenditure for Ethical Pharmaceuticals	1972	1977	1978	1979
Company-Financed R & D Expenditures for Human-Use Products				
Percentage spent in the United States	82.73%	77.11%	77.58%	76.59%
Within firm	72.52	67.60	66.19	64.31
Outside firm	10.21	9.51	11.39	12.28
Percentage spent in foreign countries	9.10	15.49	15.81	16.88
Within firm	8.03	13.03	14.10	14.95
Outside firm	1.07	2.46	1.71	1.93
TOTAL Human-Use R & D	91.83	92.60	93.39	93.47
Company-Financed R & D Expenditures for Veterinary-Use Products:				
Percentage spent in the United States	6.51	5.40	4.98	4.88
Within firm	6.03	4.81	4.44	4.39
Outside firm	.48	.59	.54	.49
Percentage spent in foreign countries	.71	1.22	1.13	1.22
Within firm	.70	1.14	1.08	1.16
Outside firm	.01	.08	.05	.06
TOTAL Veterinary R & D	7.22	6.62	6.11	6.10
TOTAL Company-Financed R & D	99.05	99.22	99.50	99.57
U.S. Government Grants and Contracts for Company-Conducted R & D	.95	.78	.50	.43
TOTAL Expenditures for R & D	100.00%	100.00%	100.00%	100.00%

Distribution of Company-Financed R & D Expenditures, Human- and Animal-Use Pharmaceuticals, 1978, by R & D Expenditure Size Group (percentages)

18

Category of Expenditure	Global R & D by Expenditure Size Group (millions of dollars) over $30	$10-30	$1-10	under $1	All Companies
Company-Financed R & D Expenditures for Human-Use Pharmaceuticals:					
Percentage spent in the United States	75.8%	81.9%	87.4%	100.0%	77.2%
Within firm	66.6	59.4	72.5	87.0	65.9
Outside firm	9.2	22.5	14.9	13.0	11.3
Percentage spent in foreign countries	17.2	15.4	4.4	–	16.4
Within firm	15.4	13.5	3.4	–	14.6
Outside firm	1.8	1.9	1.0	–	1.8
Company-Financed R & D Expenditures for Veterinary-Use Pharmaceuticals:					
Percentages spent in the United States	5.5	2.5	8.2	–	5.2
Within firm	5.0	1.9	6.8	–	4.6
Outside firm	.5	.6	1.4	–	.6
Percentage spent in foreign countries	1.5	.2	–	–	1.2
Within firm	1.4	.2	–	–	1.1
Outside firm	.1	*	–	–	.1
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%

*Less than 0.1 percent.

Distribution of Company-Financed R & D Expenditures, Human- and Animal-Use Pharmaceuticals 1978, by Sales Size Group (percentages)

Category of Expenditure	Global Sales Size Group (millions of dollars) Over $100	$30-100	Under $30	All Companies
Company-Financed R & D Expenditures for Human-Use Pharmaceuticals:				
Percentage spent in the United States	77.1%	78.4%	100.0%	77.2%
Within firm	65.8	67.2	69.2	65.9
Outside firm	11.3	11.2	30.8	11.3
Percentage spent in foreign countries	16.1	18.8	–	16.4
Within firm	14.4	16.4	–	14.6
Outside firm	1.7	2.4	–	1.8
Company-Financed R & D Expenditures for Veterinary-Use Pharmaceuticals:				
Percentage spent in the United States	5.5	2.6	–	5.2
Within firm	4.9	2.4	–	4.6
Outside firm	.6	.2	–	.6
Percentage spent in foreign countries	1.3	.2	–	1.2
Within firm	1.2	.2	–	1.1
Outside firm	.1	–	–	.1
TOTAL Company-Financed R & D Expenditures	100.0%	100.0%	100.0%	100.0%

1978 Research and Development/Sales Ratio

- The percentage of the domestic pharmaceutical sales dollar allocated to domestic R&D remained stable at 11.5%, same as for 1976 and 1977.

- Comparing global R&D with worldwide annual sales, companies with $30 to $100 million in sales have the highest ratio (15.1%). Companies with sales over $100 million show a ratio of 8.5%, companies with sales under $30 million, a 9.2% ratio.

Tables 27 and 28

R & D as a Percentage of Sales, Ethical Pharmaceuticals, 1973-1978* 27

Year	1973	1974	1975	1976	1977	1978	Annual Average 1973-1978
Ratio . . .	11.2	11.7	11.6	11.5	11.5	11.5	11.5%

*Human and veterinary ethical pharmaceuticals. R & D is domestic U.S. only as financed by companies for internal and external performance. Sales basis: Domestic sales plus exports to other firms and intrafirm exports but excluding sales of foreign plants owned by U.S. firms. For this special analysis, only data from companies furnishing complete R & D and sales information were used. There were 42 companies that responded to both the sales and R & D surveys for 1978.

Global R & D-to-Sales Ratio for Company-Financed Ethical Pharmaceuticals, 1978* (percentages) 28

	Global Sales Category			
	Under $30 million	$30-100 million	Over $100 million	All
R & D/Sales Ratio	9.2%	15.1%	8.5%	8.8%
Percentage of Firms	7.0%	31.0%	62.0%	100.0%

*Human and veterinary R & D, domestic and foreign, company-financed for internal and external performance.

1978 Average Company Research and Development Expenditures

- Companies in the top category of R&D spending worldwide (over $30 million) averaged $64 million in R&D expenditures and $758 million in global sales.
- Companies in the top category of R&D spending in the U.S. alone (over $30 million), averaged $54 million in R&D expenditures and $414 million in U.S. sales.

Tables 29 and 30

Global R & D-and-Sales Averages, Ethical Pharmaceuticals, 1978 by Global R & D Expenditure Category* (millions of dollars) 29

Global R & D Expenditure Category ($ millions)	Average Firm, Global R & D Expenditures	Average Firm, Global Sales	R & D to Sales Ratio (%)
Over $30	$64.0	$757.6	8.4%
$10-30	19.1	136.8	14.0
$1-10	5.1	76.0	6.7
Under $1	.6	18.7	3.2
AVERAGE, All Firms	$31.9	$362.0	8.8%

*Human and veterinary R & D, domestic and foreign, company-financed, for internal and external performance. Sales are domestic and foreign.

Domestic R & D-and-Sales Averages, Ethical Pharmaceuticals, 1978 by Domestic R & D Expenditure Category* (millions of dollars) 30

Domestic R & D Expenditure Category ($ millions)	Average Domestic R & D Expenditures	Average Domestic Sales	R & D to Sales Ratio (%)
Over $30	$53.8	$413.7	13.0%
$10-30	16.8	112.5	14.9
$1-10	4.9	61.8	7.9
Under $1	.6	13.2	4.6
AVERAGE, All Firms	$26.3	$205.7	12.8%

*Human and veterinary R & D, domestic only, company-financed, for internal and external performance. Sales are domestic only, exclude exports and intrafirm transactions.

1978 Research and Development Employment

- 27,875 scientists and supporting technical staff members work in pharmaceutical R&D – 22,675 (81%) in the U.S. and 5,200 (19%) abroad.
- 21% of all U.S. R&D personnel hold doctoral degrees. This percentage has changed little in the past decade.
- Scientific and professional personnel form the largest grouping of R&D employees, constituting 55% of the total in 1978.

Tables 31 and 32

1978 Research and Development Employment Costs

- Average expenditures per R&D employee range from $43,320 per employee in general, to $203,300 per employee with a doctoral degree. Highest expenditures are by companies with annual R&D spending over $40 million ($46,240 per employee in general; $216,590 per employee with a doctoral degree). Lowest expenditures are by companies with R&D spending between $10 and $40 million.
- Two-thirds of all R&D personnel are employed by companies in the highest R&D expenditure category, (over $40 million). These same companies employ a comparable share of scientific and professional, and supporting personnel, and 74 percent of the technicians.
- The industry averages 55 scientists per 100 R&D employees. The highest ratio, 63 scientists per 100 employees, is found in companies with the lowest R&D expenditures (under $10 million); the lowest ratio, 54 per 100, is found in companies with the highest R&D outlay (over $40 million.)

Tables 33 and 34

R & D Personnel in the United States, Educational and Position Levels, 1978

31

Category	Total	Doctoral Degree	Master's Degree	Bachelor's Degree	Less Than Degree
Scientific and Professional	12,480	4,400	2,665	4,715	700
Technical	4,740	0	30	410	4,300
Supporting Staff	5,455	345	350	370	4,390
TOTAL	22,675	4,745	3,045	5,495	9,390

R & D Personnel in U.S. and Abroad, 1978

32

	Grand Total	In U.S.	Abroad
Total Number Personnel	27,875	22,675	5,200
Percentage	100%	81%	19%

U.S. Intramural R & D Expenditures for Human- and Veterinary-Use Pharmaceuticals per R & D Employee, 1978*

33

R & D Expenditure Category ($ millions)	All R & D Personnel	Scientific & Professional	Doctoral Degree
Over $40 million	$46,240	$84,990	$216,590
$10-40	36,370	64,580	170,830
Under $10	43,030	67,730	205,970
AVERAGE, All Firms	$43,320	$78,160	$203,300

*These figures represent domestic intramural expenditures divided by the number of personnel in each category.

R & D Manpower by Company R & D Expenditure, 1978

34

Company R & D Expenditure Category ($ millions)	Total	Scientific & Professional	Technicians	Supporting	Scientists Per 100 R & D Personnel
Over $40 million	15,155	8,185	3,470	3,500	54
$10-40	6,305	3,530	1,045	1,730	56
Under $10	1,215	765	225	225	63
TOTAL	22,675	12,480	4,740	5,455	55

Glossary

Definitions used in the 1978-1979 Survey

Biologicals – bacterial and virus vaccine, antigens, antitoxins, toxoids, and analogous products (such as allergenic extracts), serums, plasmas, and other blood derivatives for human use.

Bulk – For use as a pharmaceutical or medicinal product in further manufacture or in packaging by another company, or for processing in animal feeds (but not as nutritional ingredients), or in prescription compounding, etc.

Company or Firm – Manufacturers including parent, affiliated and subsidiary companies, without duplication engaged in production of ethical pharmaceuticals, biologicals, diagnostic products and medical devices.

Diagnostic Agents (in vivo) – Diagnostic products used in living body.

Diagnostic Products (in vitro) – Those reagents, instruments, and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat or prevent disease or its sequelae. Such products are intended for use in the collection, preparation and examination of specimens taken from the human body.

Employment – All full-time production workers as well as officers of the company, including employees engaged in the following activities: factory supervision above the working foreman level, sales, advertising, financial, clerical, executive, purchasing, legal, personnel, professional and technical.

1. *Production Workers* – Employees up through the working foreman level engaged in fabricating, processing, assembling, receiving, inspection, quality control, handling, packing, warehousing and storage, shipping, maintenance, repair, janitorial, watchman service, production development, record keeping, and other services associated with the production operations.
2. *Medical Research and Development* – Personnel engaged in research, research administration, clinical evaluation and development; excludes personnel in promotion, sales, market research, business administration, production and quality control.
3. *Sales and Marketing Research Employees* – Personnel in sales, advertising, sales promotion, market research, etc.
4. *Administrative Employees* – Personnel responsible for general management, accounting, finance, planning, personnel, purchasing office services, legal, secretarial, etc.

Employment Abroad – Total number of full-time employees, whether U.S. citizens or not, of PMA member firms or any wholly owned overseas corporations, or corporations in which PMA member firms had a substantial or controlling interest.

Ethical Pharmaceuticals – Products, including biologicals and medicinal chemicals, used for the cure, alleviation, mitigation, treatment, prevention or diagnosis of disease in humans or animals and promoted primarily to the medical, pharmacy and allied profession; includes products for over-the-counter ethical sales as well as for ultimate dispensing by prescription only.

Exports – "F.o.b.," U.S. port.

a) To other firms: sales to third parties only.
b) Intrafirm transactions: sales and shipments at billed (not end sales) value to subsidiaries and affiliates for further handling, processing or packaging.

Government Grants and Contracts for Company-Conducted R&D – Grants and contractual payments received by companies from governmental agencies for pharmaceutical research and development.

Over-the-Counter Ethical – A drug product sold over the counter but primarily promoted to the professions.

Prescription Legend – A drug product which by Federal law is available only by prescription by a licensed physician.

Research and Development – The term includes basic and applied research as well as development activities carried on or supported in the pharmaceutical, biological, chemical, medical and related sciences, including psychology and psychiatry, if the purpose of such activities is concerned ultimately with the utilization of scientific principles in understanding diseases or in improving health.

R&D Expenditures – The total cost incurred for all pharmaceutical research and development activity, including cost of salaries, other direct costs, service, routine supplies, and supporting costs, plus a fair share of overhead (administration, depreciation, space charges, rent, etc.).

Cost of drugs or medical research and development conducted on grant or contract for other companies are excluded. Conversely, total outlays for all research and development work contracted to others (manufacturers, independent research laboratories, academic institutions, etc.) are included.

Research and Development Expenditures Within Firm – Includes research and development expenditures in the United States and foreign countries in a firm's own research laboratories.

Research and Development Expenditures Outside Firm – Research and development funds contracted or granted to such organizations as commercial laboratories, private practitioners, consultants, etc., educational institutions, non-profit research institutions, manufacturing and other companies or other research performing organizations.

R&D Manpower – Personnel engaged in research, research administration, clinical evaluation and development: excludes personnel in promotion, sales, market research, business administration, production and quality control.

Research and Development Scientific and Professional Staff – Includes all persons whose work requires the application for research and development of knowledge, skills and scientific techniques, in the life, physical, engineering, or mathematical sciences, acquired through the completion of a four-year college course (or its equivalent) with a major in these fields or in medicine or other health professions. Excludes persons who have formal training in the sciences but who are not actively engaged in research and development.

Research and Development Supporting Staff – Includes persons who provide literature, clinical statistical, or other services specifically for R&D staff and technicians.

Research and Development Technicians – Includes persons actually engaged in technical work at a level which requires knowledge of the life, physical, engineering, or mathematical sciences comparable at least to that acquired through technical institutes, junior colleges, or other formal post-high school training less extensive than four-year college training, or through equivalent on-the-job training or experience. However, also included are persons who hold an academic degree at the bachelor's level or above.

Sales – Sales figures are reported as billed (before deducting cash discounts on sales and other marketing expenses), less returns and allowances. Includes sales value of products brought and resold without further processing or repackaging as well as the dollar value of products made from own materials for other manufacturers' resale. Excluded are all royalty payments, interest and other income.

Sales Abroad – Actual sales consummated in foreign countries other than "Sales for Exports to Other Firms." Such sales by affiliates and subsidiaries or other operations abroad reported in dollars, computed at December 31, 1978 rate of exchange (when possible). Where a partially owned subsidiary is involved, the firm's share is determined on a proportionate profit-sharing basis.

Sales for Export – Reported as "f.o.b. U.S. port."

1. *To Other Firms* – excludes intracompany transactions, includes sales to third parties only.
2. *Intracompany Transactions* – includes sales and shipments to subsidiaries or affiliates for further handling, processing, or finishing by them. Reported as net billed value, not end sales values.

Sales by Product Class – Estimated distribution of domestic sales of ethical pharmaceutical and biological dosage-form preparations in accordance with the classification system used in the Annual Census "Value of Shipments of Pharmaceutical Preparations" (with the exception of "biologicals" and "diagnostic agents").

Sales to Governments – Sales or shipments made directly to federal, state or local government agencies, hospitals and clinics.

Sales to Private Sector – Sales through regular marketing channels for end-use other than by government agency administration or distribution.